

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Group Art Unit 1793	:	
	:	
Application Serial No. 10/656,918	:	
	:	
In re Application of Forbes Jones et al.	:	COBALT-NICKEL-CHROMIUM-
	:	MOLYBDENUM ALLOYS WITH
	:	REDUCED LEVEL OF TITANIUM
Filed September 5, 2003	:	NITRIDE INCLUSIONS
	:	
Examiner Jessee Roe	:	

**VIA ELECTRONIC MAIL**

Commissioner for Patents  
P.O. Box 1450  
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**APPEAL BRIEF**

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Owner of the entire interest in the above-referenced patent application (the "Present Application") submits this Appeal Brief in accordance with the provisions of 37 C.F.R. § 41.37 in response to the Office Action dated August 18, 2008, and further to the Notice of Appeal filed December 3, 2008. The Commissioner is hereby authorized to charge PTO Deposit Account No. 11-1110 for any extension of time fees and any other fees necessary for consideration of this brief and appeal.

**I. REAL PARTY IN INTEREST**

The real party in interest is ATI Properties, Inc., by reason of assignment of the Present Application and the invention from the inventors, recorded at Reel 016199, Frame 0870. ATI Properties, Inc., is a wholly-owned subsidiary of Allegheny Technologies Incorporated.

II. **RELATED APPEALS AND INTERFERENCES**

A Notice of Appeal was filed in the Present Application on December 3, 2008. Applicants are not aware of any other appeals or any interferences that may be related to, may directly affect, may be directly affected by, or may have a bearing on the decision of the Board of Patent Appeals and Interferences (the "Board") in the present appeal.

### **III. STATUS OF CLAIMS**

The Present Application was originally filed with claims 1-49. During prosecution, new claims 50-54 were added and claims 3, 9, 11, 21-31, 31 (inadvertent second occurrence), and 35-52 were cancelled. Claims 1, 2, 4-8, 10, 12-20, 32-34, 53, and 54 remain pending in the Present Application and form the basis of the present Appeal.

In the Final Office Action mailed August 18, 2008 (hereinafter "the Final Office Action"), claims 1, 2, 4-8, 10, 12, 16-20, 32-34, 53, and 54 are rejected under 35 U.S.C. § 103(a) as having been obvious over U.S. Patent No. 3,356,542 to Smith (hereinafter "Smith"). Also, in the Final Office Action claims 13-15 are rejected under § 103(a) as having been obvious over Smith as applied to claim 1, and further in view of U.S. Patent No. 4,820,485 to Ototani et al. (hereinafter "Ototani"). In addition, in the Final Office Action claims 20, 32-34, and 54 are rejected under § 103(a) as having been obvious over Smith as applied to claim 1, and further in view of U.S. Patent No. 6,342,068 to Thompson (hereinafter "Thompson").

Accordingly, claims 1, 2, 4-8, 10, 12-20, 32-34, 53, and 54 stand rejected and are subject to appeal. The text of these rejected claims is set forth in the Claims Appendix in Section VIII of the present Appeal Brief.

**IV. STATUS OF AMENDMENTS**

All amendments previously submitted in the Present Application have been entered. No amendments were submitted in the Present Application subsequent to the Final Office Action.

**V. SUMMARY OF CLAIMED SUBJECT MATTER**

All references herein to the specification of the Present Application refer to the numbered paragraphs of the Present Application as published (Pub. No. 2005-0051243 A1). The claims under consideration in the present Appeal arguably include two independent claims, which are claims 1 and 32. These claims read as follows:

1. An alloy having favorable fatigue resistance and comprising:  
at least 20 weight percent cobalt;  
32.7 to 37.3 weight percent nickel;  
18.75 to 21.25 weight percent chromium;  
8.85 to 10.65 weight percent molybdenum; and  
less than 30 ppm nitrogen;  
less than 0.7 weight percent titanium;  
at least one of at least 0.05 to 0.15 weight percent aluminum, at least 5 to 20 ppm calcium, at least 5 to 50 ppm magnesium, and at least 5 to 50 ppm cerium; and  
no greater than 1.05 weight percent iron;  
no greater than 0.035 weight percent carbon; and  
wherein the alloy includes generally spherical oxide inclusions and is substantially free of titanium nitride and mixed metal carbonitride inclusions.
32. An article of manufacture comprising the alloy of any of claims 1, 2, 4-8, 10, and 12-20.

Therefore, claim 1 is directed to an alloy having favorable fatigue resistance and the composition recited in the claim, and wherein the alloy also "includes generally spherical oxide inclusions and is substantially free of titanium nitride and mixed metal carbonitride inclusions."

Claim 32 is directed to an article of manufacture including the alloy recited in any of claim 1 or various other dependent claims which directly or ultimately depend from claim 1.



## VI. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

1. Rejection of claims 1, 2, 4-8, 10, 12, 16-20, 32-34, 53, and 54 under 35 U.S.C. § 103(a) as having been obvious over U.S. Patent No. 3,356,542 to Smith (hereinafter "Smith"). Appellant submits that the Examiner did not establish a *prima facie* case of obviousness.

2. Rejection of claims 13-15 under § 103(a) as having been obvious over Smith as applied to claim 1, and further in view of U.S. Patent No. 4,820,485 to Ototani et al. (hereinafter "Ototani"). Appellant submits that the Examiner did not establish a *prima facie* case of obviousness.

3. Rejection of claims 20, 32-34, and 54 are rejected under § 103(a) as having been obvious over Smith as applied to claim 1, and further in view of U.S. Patent No. 6,342,068 to Thompson ("hereinafter "Thompson"). Appellant submits that the Examiner did not establish a *prima facie* case of obviousness.

4. Conclusion of the Examiner that the evidence of record of the secondary considerations of long-felt and unmet need, surprising and unexpected results, and/or commercial success did not rebut any *prima facie* case of obviousness that the Examiner did establish against any of the pending claims. Appellant submits that the evidence of secondary consideration of nonobviousness was sufficient to rebut any *prima facie* case of obviousness that may have been established.

## VII. ARGUMENT

### 1. **The Examiner Did Not Establish a *Prima Facie* Case Under § 103(a) that Claims 1, 2, 4-8, 10, 12, 16-20, 32-34, 53, and 54 Would Have Been Obvious over Smith**

In the Final Office Action, the Examiner maintained his earlier rejection of claims 1, 2, 4-8, 10, 12, 16-20, and 32-34 under § 103(a) as having been obvious over Smith. Of these rejected claims, claims 1 and 32 are the independent claims. For at least the following reasons, Appellant submits that a *prima facie* case of obviousness for rejecting any of these claims over Smith was not established.

#### A. **The History of Development and the Significance of the Claimed Invention**

Putting Appellant's arguments regarding nonobviousness and secondary consideration in proper context will be aided by the following discussion of the development and significance of the alloy recited in claim 1. This discussion was presented to the Examiner in the "Declaration of Henry E. Lippard, Ph.D." (hereinafter "the Lippard Declaration", attached hereto as Exhibit 1) and in a "Response to Office Action", both submitted in the Present Application on August 24, 2007.

The story of how the claimed alloy was invented began with a long-felt but as-yet-unmet need for improved small diameter MP35N alloy wire for use in the cardiac pacemaker lead industry and, more generally, in the surgical implant industry. As discussed in the Present Application, MP35N alloy (UNS R30035) is a specialized cobalt-nickel-chromium-molybdenum alloy produced in bar and wire form and used in surgical implant applications. Such applications include, for example, cardiac stents and cardiac pacing leads for relaying pacing pulses from an implanted defibrillator or pacemaker to the heart. Standard specifications for wrought MP35N alloy for use in surgical implant applications are found in ASTM specification F 562, and ASTM specification F 562-02 was incorporated by reference into the Present Application. As used in the Present Application, "MP35N" alloy refers to an alloy having the chemical

composition described in Table 1 of the Present Application and in the ASTM specification.

Significant existing drawbacks of surgical implant-gauge wire produced from conventional MP35N alloy are discussed in paragraph 0003 of the Present Application as follows:

[0003] Certain technical problems may be encountered during the manufacture of MP35N alloy for use in pacing leads and other surgical implant applications. In particular, problematic surface defects may appear when cold drawing the alloy to wire. When drawing the alloy to small gauge wire for use as pacing leads, for example, surface defects are most likely to develop during the late stages of the drawing process, when the wire approaches the 0.007 inch diameter final size typically used for such applications. Drawing-related surface defects are particularly problematic because they may appear after significant time and money are invested in the product. As the wire approaches small diameter, the surface defects may cause the wire to fracture during cold drawing. This results in lower process yields during production, which can significantly increase the cost of the wire. Pacing leads and other surgical implants formed from MP35N alloy wire having surgical defects also may have reduced fatigue resistance and may be susceptible to fracture. The resultant reduced service life may require premature replacement of the implant.

Against this backdrop, the present inventors set to work to identify and address the phenomenon responsible for the industry-recognized sub-par mechanical performance of conventional MP35N wire. The present inventors discovered that titanium nitride (TiN) and mixed metal carbonitride inclusions present in conventional MP35N alloys are problematic because they are generally large and have a cuboidal morphology that mechanically scores the surfaces of drawing dies used to make small-diameter wire from the alloy. It was the present inventors who initially discovered a link between the presence and morphology of titanium nitride and mixed metal carbonitride inclusions in conventional MP35N alloy and the mechanical performance of MP35N alloy in certain surgical implant applications, such as in pacing leads. As explained in the following paragraphs 0033-0034 of the Present Application, the present inventors

realized that the presence and morphology of the above-mentioned titanium nitride and mixed metal carbonitride inclusions was the source of conventional MP35N alloy's poor mechanical performance:

[0033] It has been determined that the poor performance of MP35N alloy during cold drawing and forging [relates] to the presence of large, hard titanium nitride (TiN) inclusions. Also, in MP35N alloys including relatively high nitrogen levels, large, hard cuboidal mixed metal carbonitride inclusions may form in the alloys. The mixed metal carbonitrides are principally titanium and chromium carbonitrides. The principal failure mechanism of the conventional MP35N alloy upon drawing and forging is fatigue initiation at the particulate inclusions. The TiN and mixed metal carbonitride inclusions may form during solidification of the alloy after melting, and the particles cannot be removed or broken up by the subsequent heat treatment or thermomechanical processing. Instead, it has been determined that the inclusions are retained in their as-cast size in the final product.

[0034] The hard TiN and mixed metal carbonitride particles damage the drawing die during cold drawing of conventional MP35N material. Wire drawn through a damaged die may have surface defects in the form of scratches on the wire surface. Die damage and resulting wire surface defects significantly reduce yield. As the drawn wire becomes smaller in diameter, the nitride and carbonitride particles take up a larger portion of the wire cross-section and, therefore, weaken the material, thus creating fractures during drawing. The particles also act as stress raisers during fatigue loading and contribute to the initiation of fatigue cracks, which can result in the premature failure of the material and the associated device.

Thus, the present inventors determined that scoring of the wire drawing dies by the inclusions in conventional MP35N alloy produces surface defects on the drawn wire, which can cause the wire to fracture when further drawn or mechanically processed or, more critically, when subjected to fatigue over time in the body of a patient. The present inventors also concluded that the titanium nitride and mixed metal carbonitride inclusions themselves in conventional MP35N alloy wire can create points of localized stress in the drawn wires, resulting in or contributing to wire breakage during drawing or when implanted and in use in the body of a patient.

Having made these discoveries, the present inventors set to work attempting to produce a modified form of the MP35N alloy that did not suffer from these deficiencies. The present inventors unexpectedly discovered that a modified MP35N-type alloy that includes, *inter alia*, less than 30 ppm nitrogen, less than 0.7 weight percent titanium, and minor but critical amounts of at least one of aluminum, calcium, magnesium, and cerium has a microstructure that is substantially free of the problematic titanium nitride and mixed metal carbonitride inclusions the inventors had identified. Instead, the modified alloy composition includes well-tolerated relatively small, generally spherical oxide inclusions. This substantial change in microstructure was unexpected and significant – the inventors observed that the spherical oxide inclusions in the modified alloy did not significantly score wire drawing dies, reducing the incidence of surface defects on wire drawn through the dies, and also did not produce regions of substantially increased stress within the drawn wire. This was not merely a slight adjustment to the microstructure of the conventional MP35N alloy, but instead was a significant technical breakthrough that produced a fundamentally different alloy microstructure. The fundamentally different microstructure of the claimed alloy directly addressed microstructural drawbacks that the inventors discovered were present in the conventional MP35N alloy, as discussed above.

Moreover, as discussed in paragraphs 0075 to 0080 of the Present Application, as a result of the microstructural changes the present inventors produced, small-diameter wire produced from the alloy recited in claim 1 was found to exhibit unexpected and substantially improved fatigue resistance relative to conventional MP35N alloy. For example, Table 9 of the Present Application shows that at 100 ksi, a stress level similar to that to which pacing leads are subjected *in vivo*, wire formed from the alloy of the present invention withstood at least 797% the number of cycles in rotary beam fatigue testing than wire produced from conventional MP35N alloy. Also, the alloy developed by the present inventors exhibited a fatigue endurance limit of between 100-110 ksi versus the 90 ksi limit of the conventional alloy.

As was explained to the Examiner during prosecution of the Present Application, the significance of the substantial improvement in fatigue properties of the alloy recited

in claim 1 relative to conventional MP35N alloy cannot be overstated and could not have been predicted, even from the significant change in alloy microstructure observed to result from the invention. The substantial improvement in fatigue resistance is especially significant in light of the critical nature of application for cardiac pacemaker leads that are fabricated from small diameter MP35N wire. An end of a cardiac pacemaker lead is inserted directly into the heart muscle and conducts current from the pacemaker to the heart, continuously regulating the heartbeat – as one can imagine, fracture of an implanted cardiac pacemaker lead can have severe consequences, and it is of great importance (especially to the patient) to increase the service lifetime of the leads as long as possible so as to postpone replacement surgery.

Therefore, prior to the present inventors' discovery of the underlying reasons for the above-discussed failure mechanism in conventional MP35N alloy wire, there existed no clear understanding of the deficiencies in the microstructure of the conventional alloy wire used in pacemaker lead wires and in other surgical implant applications that contributed to the sub-par mechanical performance of wire made from MP35N alloy.

Because the problems inherent in conventional MP35N alloy were not known before being discovered by the present inventors, there existed no motivation or suggestion to modify the composition of conventional MP35 alloy so that it substantially lacked titanium nitride and mixed metal carbonitride inclusions and, instead, included generally spherical oxide inclusions, as recited in claim 1.

In addition, there would certainly have existed no motivation to take the specific steps, such as reducing nitrogen content to less than 30 ppm and making other modifications to alloy chemistry and processing, which the inventors discovered avoids the problematic microstructure present in conventional MP35N alloy.

As discussed below in Section VII.D.2. of this Appeal Brief, the present inventors' discoveries, once they set upon addressing the microstructural deficiencies they identified in conventional MP35N alloy, were both unexpected and significant. The present inventors unexpectedly discovered that the alloy recited in claim 1, which includes very low levels of nitrogen, limited levels of titanium, and the addition of minor

amounts of one or more of aluminum, calcium, magnesium, and cerium, substantially lacks problematic large cuboidal titanium nitride and mixed metal carbonitride inclusions. In addition, small diameter wire drawn from the claimed alloy exhibits a substantial and unexpected improvement in fatigue resistance, which significantly improves wire yield and service lifetime in pacemaker lead and other surgical implant applications.

As discussed below in Section VII.D.3. of this Appeal Brief, the significantly improved performance of wire produced from the alloy recited in claim 1 relative to conventional MP35N alloy resulted in substantial commercial success. On September 20, 2007, Applicants submitted a "Supplemental Response to Office Action" including a "Declaration of Robert J. Myers" (hereinafter "the Myers Declaration, attached hereto as Exhibit 2). As discussed in the Myers Declaration and in Office Action responses submitted on September 20, 2007 and May 28, 2008, the Myers Declaration establishes that (1) small diameter wire produced from the alloy recited in claim 1 enjoyed very substantial commercial success, and (2) the commercial success is directly attributable to the unexpected and substantial improvement in fatigue resistance of wire made according to the claims of the Present Application.

With the above background in mind, Appellant now addresses the specific rejections included in the Final Office Action.

**B.     The § 103(a) Rejection of Claim 1  
Over Smith Should be Reversed**

In the Final Office Action, the Examiner rejects claims 1, 2, 4-8, 10, 12, 16-20, 32-34, 53, and 54 under § 103(a) as having been obvious over Smith. Appellant respectfully submits that the Examiner did not satisfy the burden required to a *prima facie* case of obviousness over Smith.

Regarding independent claim 1, in the Final Office Action (page 3) the Examiner asserts that the alloy composition described in Smith "overlaps the composition of the claimed invention." The Examiner further asserts in the Final Office Action (page 3) that a *prima facie* case of obviousness exists because "[i]t would have been obvious to one

of ordinary skill in the art at the time the invention was made to select the claimed compositions of an alloy from the composition disclosed by [Smith] because [Smith] discloses the same utility (alloy wire) throughout the disclosed ranges."

Regarding the limitations recited in claim 1 that the alloy includes "at least one of at least 0.05 to 0.15 weight percent aluminum, at least 5 to 20 ppm calcium, at least 5 to 50 ppm magnesium, and at least 5 to 50 ppm cerium", as well as "no greater than 0.035 weight percent carbon", in the Final Office Action (page 4) the Examiner argues that Smith discloses adding 0 to 2 weight percent aluminum and no more than 0.05 weight percent of carbon, boron, oxygen, nitrogen, or beryllium to the alloy described in Smith "that would form a wire or cable".

Regarding the limitation recited in claim 1 that the alloy "includes generally spherical oxide inclusions and is substantially free of titanium nitride and mixed metal carbonitride inclusions", in the Final Office Action (pages 3-4) the Examiner concedes that Smith does not disclose this aspect. The Examiner, however, asserts that the alloy of Smith can lack titanium, nitrogen, and carbon and can be prepared by arc melting or induction melting in a vacuum and, thus, "it would be expected that the alloys of [Smith] would have generally spherical oxide inclusions and be substantially free of titanium nitride and mixed metal carbonitride inclusions."

The test for patentability under § 103(a) requires that: the scope and content of the prior art be determined; the differences between the prior art and the claims at issue be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. See MPEP § 2141. Further, in order to properly formulate a rejection under § 103(a), all the claim elements and limitations must be taught or suggested by the asserted prior art. See, e.g., MPEP § 2143.03. Further still, in formulating a rejection under § 103(a), the Office must identify in an Office Action a rational basis why a person of ordinary skill in the art would have combined or modified the prior art elements in the manner claimed. MPEP § 2141; *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 418 (2007) (a patent examiner must provide "an apparent reason to combine the known elements in



the fashion claimed by the patent at issue. To facilitate this review, this analysis should be made explicit.”); *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (cited with approval in *KSR*) (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”)

In the Final Office Action, the Examiner apparently concludes that he has established a *prima facie* case that the alloy recited in claim 1 would have been obviousness in light of Smith. Applicants disagree and assert that the Examiner has not established a *prima facie* case of obviousness based on Smith because Smith neither teaches nor suggests all of the elements and limitations of claim 1 of the Present Application. Claim 1 of the Present Application is directed to an alloy including, among other things, “less than 30 ppm nitrogen”. However, Smith only briefly refers to nitrogen in the following sentence appearing at col. 4, lines 68-72:

It is critically important that the alloy composition contain no more than 0.05% of carbon, boron, oxygen, nitrogen, or beryllium, the total of these components being no more than 0.1%.

This sentence of Smith merely describes an upper limit for nitrogen in the alloy. That limit is 0.05%, which is 500 ppm, a value that is more than 16 times greater than the critical value of less than 30 ppm discovered by the present inventors and recited in claim 1. Smith does not describe or suggest an alloy including less than 30 ppm of nitrogen, as is recited in claim 1. Nor does Smith in any way teach or suggest any benefit to limiting the nitrogen content of the Smith alloy to less than 30 ppm, or even to very minor concentrations. Instead, Smith simply teaches maximum levels of various incidentals, and in no way focuses on nitrogen as being particularly important relative to the other listed elements.

In short, the Examiner reads the above-quoted sentence of Smith as referring to a nitrogen range of 0 up to 500 ppm. Appellant submits that that interpretation of Smith is incorrect.

Even if it can be said that the statement in Smith that the Smith alloy contains "no more than 0.05%" (500 ppm) of nitrogen includes the complete absence (0%) of nitrogen (which Appellant does not concede), that statement is not sufficiently specific to teach or suggest the limitation "less than 30 ppm nitrogen", a limitation which the inventors have discovered is critical to the performance of the claimed alloy. See MPEP 2131.03 ("If the claims are directed to a narrow range, [and] the reference teaches a broad range, ... [i]t may be reasonable to conclude that the narrow range is not disclosed with 'sufficient specificity' to constitute an anticipation of the claims." (citing *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 999 (Fed. Cir. 2006))).

The *Atofina* decision cited in MPEP § 2131.03 is particularly pertinent here.<sup>1</sup> In *Atofina* the U.S. Court of Appeals for the Federal Circuit considered whether a prior art reference's teaching of a temperature range of 100 to 500°C effectively disclosed the 330 to 450°C temperature range recited in a claim. The court held that it did not, even though the claimed range was fully encompassed by the prior art range:

Here, the prior art, JP 51-82250, discloses a temperature range of 100 to 500°C which is broader than and fully encompasses the specific temperature range claimed in the '514 patent of 330 to 450°C. Given the considerable difference between the claimed range and the range in the prior art, no reasonable fact finder could conclude that the prior art describes the claimed range with sufficient specificity to anticipate this limitation of the claim. Because the court's determination that JP 51-82250 disclosed the temperature range in claims 1, 2, 6, 7, 9, and 10 of the '514 patent was [erroneous], we must reverse its finding of anticipation based on the temperature range.

*Atofina*, 441 F.3d at 999 (emphasis added). The *Atofina* court went even further – in discussing a second prior art reference that referred to a temperature range of 150 to 350°C, the court held:

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<sup>1</sup> In the "Response to Arguments" section of the Final Office Action (page 10), the Examiner argues that MPEP § 2131 is inapposite because it addresses anticipation, and not obviousness. However, Appellant respectfully submits that *Atofina* essentially addresses how a prior art reference that discloses a range may be applied in an art-based rejection such as the present rejection over Smith.

[T]he disclosure of a range of 150 to 350°C does not constitute a specific disclosure of the endpoints of that range, i.e., 150°C and 350°C, as Great Lakes asserts. The disclosure is only that of a range, not a specific temperature in that range, and the disclosure of a range is no more a disclosure of the end points of the range than it is of the intermediate points.

441 F.3d at 1000 (emphasis added).

Thus, a prior art reference disclosing a broad range must expressly or implicitly refer to a sub-range with a relatively high degree of specificity to support the rejection of a claim reciting the sub-range. For example, as the holding in *Atofina* demonstrates, it is even the case that a range described in a prior art reference does not necessarily teach the endpoints of the stated range with the requisite "sufficient specificity".

Echoing the Federal Circuit's interpretation in *Atofina*, MPEP § 2131.03 explains that the question of what constitutes "sufficient specificity" is similar to that of whether a generic teaching "clearly envisages" a species. This is discussed in MPEP § 2131.02 as follows:

If one of ordinary skill in the art is able to 'at once envisage' the specific compound within the generic chemical formula, the compound is anticipated. One of ordinary skill in the art must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be 'at once envisaged.' ...

Clearly, claim 1 of the Present Application claims a very narrow range (up to 30 ppm nitrogen) while, at least in relative terms, Smith refers to a very broad range ("no more than" 500 ppm nitrogen). It is appropriate to adopt here the Federal Circuit's reasoning in *Atofina*: "Given the considerable difference between the claimed range and the range in the prior art, no reasonable fact finder could conclude that the prior art describes the claimed range with sufficient specificity to anticipate..." (see *Atofina*, *supra*) the nitrogen limitation recited in claim 1 of the Present Application. One considering Smith's disclosure of a range of "no more than" 500 ppm would not "at once envisage" the recited range of less than 30 ppm nitrogen. Moreover, even if we assume for sake of argument that Smith teaches a range of with an upper limit of 500 ppm

nitrogen, such a teaching does not mean that Smith teaches a 0 ppm nitrogen endpoint, as the Examiner suggests. Therefore, in keeping with the law as set out in *Atofina* and in MPEP § 2131.02, Smith does not teach, nor does it suggest, a nitrogen range of less than 30 ppm.

Indeed, during prosecution before the Examiner, Applicants established that one having ordinary skill would have considered Smith as teaching an alloy that necessarily included well in excess of 30 ppm nitrogen, despite the statement in Smith that the Smith alloy should include "no more than 0.05%" nitrogen. Applicants submitted the Lippard Declaration, attached hereto as Exhibit 1, with the August 24, 2007 response. The Lippard Declaration addresses what one having ordinary skill would have been taught by Smith regarding nitrogen content in the alloy of Smith. The Lippard Declaration confirms that at the time the Present Application was filed one having ordinary skill would not have read Smith to teach or suggest limiting nitrogen in the Smith alloy to less than 30 ppm. Specifically, the Lippard Declaration includes the following uncontradicted statements directed to the nitrogen concentration of Smith:

12. I have thoroughly reviewed U.S. Patent No. 3,356,542 issued to Smith ("Smith"). Smith does not describe or suggest an alloy that includes less than 30 ppm of nitrogen. Although Smith does state that the alloy described in that patent should include "no more than 0.05%" nitrogen, that level is more than 15 times the maximum nitrogen level critical to the invention described in the Application. Smith does not describe or suggest that there is any benefit whatsoever to limiting the nitrogen level in the alloy of that patent to less than 30 ppm, or even to very small, ppm range, concentrations.

13. Given that Smith does not state or suggest that the alloy in that patent has or would benefit from having less than 30 ppm nitrogen, or even very low (ppm range) nitrogen levels, the alloy of Smith would certainly have included at least 50 ppm nitrogen. For example, 50 ppm is the minimum level of nitrogen found in conventional MP35N alloy. Although Smith does refer offhand to vacuum melting, such techniques were well known at the time, and Smith does not state or suggest that melting under vacuum should be done for reducing alloy nitrogen levels or otherwise. Smith does not state or suggest any reason why one would have undertaken the involved, time-consuming, and costly

steps necessary to limit nitrogen in the alloy described in Smith to less than 30 ppm or to any other extremely low level.

14. Absent limiting nitrogen to these very low levels recited in claim 1, alloy microstructure could not be substantially free of titanium nitride and mixed metal carbonitride inclusions. Also, Smith does not specifically describe or otherwise suggest a microstructure that is substantially free of titanium nitride and mixed metal carbonitride inclusions. Accordingly, Smith does not teach or suggest an alloy having a microstructure that is substantially free of titanium nitride and mixed metal carbonitride inclusions and, instead, includes well-tolerated substantially spherical oxide inclusions, as is recited in claim 1.

Therefore, in his declaration, Dr. Lippard, who is one having at least ordinary skill in the art, attests that Smith does not describe or suggest a nitrogen level of less than 30 ppm. Further, Dr. Lippard explains that the alloy of Smith necessarily would have included at least 50 ppm nitrogen, which, as discussed in the specification of the Present Application, is the minimum level of nitrogen that was found in a conventional MP35N alloy prior to the present invention and at the time of Smith. Absent some identified motivation to take the extraordinary steps of the present inventors to limit nitrogen in the alloy of claim 1 to extremely low levels, less than 30 ppm, the alloy of Smith would include a significantly greater nitrogen concentration due to, for example, nitrogen in the raw materials and in the furnace atmosphere. Again, Smith does not describe or suggest any reason why one of ordinary skill would take the significant and costly steps to limit nitrogen in the Smith alloy to such extremely low levels of less than 30 ppm. Therefore, the Examiner's references to the nitrogen range of Smith as "0-0.05" in the Tables included on pages 2 and 3 of the Final Office Action do not accurately characterize the teaching of Smith. Absent restricting nitrogen content to less than 30 ppm, as is recited in claim 1, one also could not develop the microstructure that is specifically recited in claim 1.

In the Final Office Action, the Examiner only refers to the Lippard Declaration as being from an inventor named in the Present Application, but does not address the declaratory evidence presented in the declaration regarding the teaching of Smith. (See, for example, page 11 of the Final Office Action.) The Examiner, however, is

required to carefully weigh the uncontroverted statements regarding Smith in the Lippard Declaration. MPEP § 2145, for example, states that “[c]onsideration of rebuttal evidence and arguments requires Office personnel to weigh the proffered evidence and arguments”, and that “Office personnel should avoid giving evidence no weight, except in rare circumstances.” MPEP § 2145 also explains:

Office personnel should consider all rebuttal arguments and evidence presented by applicants. *See, e.g.,* *Soni*, 54 F.3d at 750, 34 USPQ2d at 1687 (error not to consider evidence presented in the specification). *C.f., In re Alton*, 76 F.3d 1168, 37 USPQ2d 1578 (Fed. Cir. 1996) (error not to consider factual evidence submitted to counter a 35 U.S.C. 112 rejection); *In re Beattie*, 974 F.2d 1309, 1313, 24 USPQ2d 1040, 1042-43 (Fed. Cir. 1992) (Office personnel should consider declarations from those skilled in the art praising the claimed invention and opining that the art teaches away from the invention.); *Piasecki*, 745 F.2d at 1472, 223 USPQ at 788 (“[Rebuttal evidence] may relate to any of the *Graham* factors including the so-called secondary considerations.”). ...

[Rebuttal evidence] may also include evidence of the state of the art, the level of skill in the art, and the beliefs of those skilled in the art. *See, e.g., In re Oelrich*, 579 F.2d 86, 91-92, 198 USPQ 210, 214 (CCPA 1978) (Expert opinions regarding the level of skill in the art were probative of the nonobviousness of the claimed invention.) ....

Appellant respectfully submits that the Examiner has neither afforded proper weight to nor otherwise considered the evidence presented in the Lippard Declaration when assessing what is taught or suggested by Smith. The Lippard Declaration includes uncontroverted statements of a technical nature, made by one having at least ordinary skill, regarding the state of the art at the time of Smith. As there is no basis in the record to ignore or devalue the statements in the Lippard Declaration, those statements should be accepted at face value. *See, e.g.,* MPEP § 716.02(g) (“The reason for requiring evidence in declaration or affidavit form is to obtain the assurances that any statements or representations made are correct, as provided by 35 U.S.C. 25 and 18 U.S.C. 1001.” (emphasis added)).

Given the rejections in the Final Office Action, the Examiner apparently concludes that despite (1) Dr. Lippard’s uncontroverted statements of the then-existing

state of the art and understanding of ordinarily skilled persons in the art, and (2) the holdings of the Federal Circuit and the directives of the MPEP discussed above, Smith nevertheless teaches the recited nitrogen range simply because it arguably teaches, without elaboration, that the Smith alloy should include “no more than 0.05%” (500 ppm nitrogen). That conclusion cannot be maintained and should be reversed by the Board.

Therefore, Appellant respectfully submits that Smith does not disclose, does not suggest, and would not have included an alloy including less than 30 ppm nitrogen. It follows that the Examiner has not established a *prima facie* case that the invention recited in claim 1 of the Present Application would have been obvious over Smith since such a rejection requires that all the claim limitations, including the limitation of less than 30 ppm nitrogen, are taught or suggested by the cited prior art. MPEP § 2143.03.

Absent limiting nitrogen to the very low level of less than 30 ppm, in conjunction with certain other recited limitations of the composition, the alloy microstructure would not be substantially free of titanium nitride and mixed metal carbonitride inclusions, as is recited in claim 1. Additionally, in the Final Office Action (page 3) the Examiner concedes that Smith does not specifically teach a microstructure that is substantially free of titanium nitride and mixed metal carbonitride inclusions. Accordingly, Smith also does not disclose, does not suggest, and would not have included an alloy having a microstructure that is substantially free of titanium nitride and mixed metal carbonitride inclusions and that, instead, includes well-tolerated substantially spherical oxide inclusions, as is recited in claim 1.

In the Final Office Action (page 11), the Examiner argues that “[w]ith respect to the amount of nitrogen, the normal desire of scientists or artisans to improve upon what is already known provides motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.” Here, however, Smith does not disclose an alloy including anywhere from 0 up to 500 ppm (0.05%) nitrogen. Instead, as discussed above, one having ordinary skill would not have interpreted Smith as teaching anything more than an alloy including as much as 500 ppm nitrogen and, perhaps, as little as the conventional minimum level of 50 ppm nitrogen.

As discussed in Section VII.1.A. above, prior to the present inventors' discovery of the underlying reasons for the sub-par mechanical performance of wire formed from conventional MP35N alloy, there existed no clear understanding of the deficiencies in the conventional alloy's microstructure when formed into wire used in cardiac pacemaker lead wires and in other surgical implant applications. Because the problems inherent in conventional MP35N alloy were not known before being discovered by the present inventors, there would have existed no motivation or suggestion to modify the microstructure of the Smith alloy so that it substantially lacked titanium nitride and mixed metal carbonitride inclusions and, instead, includes generally spherical oxide inclusions, as recited in claim 1. In addition, there would certainly have existed no motivation to take the specific steps, such as reducing nitrogen content to less than 30 ppm and making other modifications to alloy chemistry and processing, which the inventors discovered avoids the problematic microstructure present in conventional MP35N alloy. Moreover, the inventors' discoveries, once they set upon addressing the microstructural deficiencies they identified in MP35N alloy, were both unexpected and significant.

In the Final Office Action, the Examiner reaches a sweeping and unsupported conclusion that the broad alloy composition he asserts Smith discloses would have rendered obvious the much narrower composition recited in claim 1. As discussed above, the present inventors discovered that the alloy composition recited in claim 1 is critical to the significantly enhanced mechanical performance of the alloy. Selecting the recited alloy composition out of what is purportedly disclosed in Smith was not taught or suggested by Smith. Instead, the Examiner's § 103(a) rejection of claim 1 over Smith amounts to impermissible hindsight – the Examiner impermissibly concludes that the claimed invention would have been obvious based on the present inventors' revelation, in the Present Application, that the invention recited in claim 1 provides significant advantages. See *KSR Int'l*, 550 U.S. at 421 ("A fact finder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments relying on *ex post* reasoning."); *Graham v. John Deere Co.*, 383 U.S. 1, 36 (1966) (warning against a "temptation to read into the prior art the teachings of the invention in issue" and instructing the courts to "guard against slipping into the use of hindsight" (quoting



*Monroe Auto Equipment Co. v. Heckethorn Mfg. & Supply Co.*, 332 F.2d 406, 412 (6th Cir. 1946)); *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983) ("It is difficult but necessary that the decisionmaker forget what he or she has been taught ... about the claimed invention and cast the mind back to the time the invention was made (often as here many years), to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art.")

Therefore, for at least the reasons discussed above, the Examiner has not established a *prima facie* case of obviousness relative to claim 1 of the Present Application. The Examiner's rejection of claim 1 should be reversed and the claim should be allowed.

**C.     The § 103(a) Rejection of Claim 2  
Over Smith should be Reversed**

Claim 2 depends directly from claim 1 and, therefore, incorporates all of the alloy composition and microstructure limitations recited in claim 1. Because it has been shown above that the Examiner did not meet his burden to establish a *prima facie* case that the invention recited in claim 1 would have been obvious over Smith, it follows that the Examiner's § 103(a) rejection of claim 2 over Smith also should be reversed, and claim 2 should be allowed.

**D.     The § 103(a) Rejection of Claim 4  
Over Smith should be Reversed**

Claim 4 depends directly from claim 1 and, therefore, incorporates all of the alloy composition and microstructure limitations recited in claim 1. Because it has been shown above that the Examiner did not meet his burden to establish a *prima facie* case that the invention recited in claim 1 would have been obvious over Smith, it follows that the Examiner's § 103(a) rejection of claim 4 over Smith also should be reversed, and claim 4 should be allowed.

**E.     The § 103(a) Rejection of Claim 5  
Over Smith should be Reversed**

Claim 5 depends directly from claim 1 and, therefore, incorporates all of the alloy composition and microstructure limitations recited in claim 1. Because it has been shown above that the Examiner did not meet his burden to establish a *prima facie* case that the invention recited in claim 1 would have been obvious over Smith, it follows that the Examiner's § 103(a) rejection of claim 5 over Smith also should be reversed, and claim 5 should be allowed.

**F.     The § 103(a) Rejection of Claim 6  
Over Smith should be Reversed**

Claim 6 depends directly from claim 1 and, therefore, incorporates all of the alloy composition and microstructure limitations recited in claim 1. Because it has been shown above that the Examiner did not meet his burden to establish a *prima facie* case that the invention recited in claim 1 would have been obvious over Smith, it follows that the Examiner's § 103(a) rejection of claim 6 over Smith also should be reversed, and claim 6 should be allowed.

**G.     The § 103(a) Rejection of Claim 7  
Over Smith should be Reversed**

Claim 7 depends directly from claim 1 and, therefore, incorporates all of the alloy composition and microstructure limitations recited in claim 1. Because it has been shown above that the Examiner did not meet his burden to establish a *prima facie* case that the invention recited in claim 1 would have been obvious over Smith, it follows that the Examiner's § 103(a) rejection of claim 7 over Smith also should be reversed, and claim 7 should be allowed.

**H.     The § 103(a) Rejection of Claim 8  
Over Smith should be Reversed**

Claim 8 ultimately depends from claim 1 and, therefore, incorporates all of the alloy composition and microstructure limitations recited in claim 1. Because it has been

shown above that the Examiner did not meet his burden to establish a *prima facie* case that the invention recited in claim 1 would have been obvious over Smith, it follows that the Examiner's § 103(a) rejection of claim 8 over Smith also should be reversed, and claim 8 should be allowed.

**I.     The § 103(a) Rejection of Claim 10  
Over Smith should be Reversed**

Claim 10 ultimately depends from claim 1 and, therefore, incorporates all of the alloy composition and microstructure limitations recited in claim 1. Because it has been shown above that the Examiner did not meet his burden to establish a *prima facie* case that the invention recited in claim 1 would have been obvious over Smith, it follows that the Examiner's § 103(a) rejection of claim 10 over Smith also should be reversed, and claim 10 should be allowed.

**J.     The § 103(a) Rejection of Claim 16  
Over Smith should be Reversed**

Claim 16 depends directly from claim 1 and, therefore, incorporates all of the alloy composition and microstructure limitations recited in claim 1. Because it has been shown above that the Examiner did not meet his burden to establish a *prima facie* case that the invention recited in claim 1 would have been obvious over Smith, it follows that the Examiner's § 103(a) rejection of claim 16 over Smith also should be reversed, and claim 16 should be allowed.

**K.     The § 103(a) Rejection of Claim 17  
Over Smith should be Reversed**

Claim 17 depends directly from claim 1 and, therefore, incorporates all of the alloy composition and microstructure limitations recited in claim 1. Because it has been shown above that the Examiner did not meet his burden to establish a *prima facie* case that the invention recited in claim 1 would have been obvious over Smith, it follows that the Examiner's § 103(a) rejection of claim 17 over Smith also should be reversed, and claim 17 should be allowed.

**L.     The § 103(a) Rejection of Claim 18  
         Over Smith should be Reversed**

Claim 18 depends directly from claim 1 and, therefore, incorporates all of the alloy composition and microstructure limitations recited in claim 1. Because it has been shown above that the Examiner did not meet his burden to establish a *prima facie* case that the invention recited in claim 1 would have been obvious over Smith, it follows that the Examiner's § 103(a) rejection of claim 18 over Smith also should be reversed, and claim 18 should be allowed.

**M.     The § 103(a) Rejection of Claim 19  
         Over Smith should be Reversed**

Claim 19 depends directly from claim 1 and, therefore, incorporates all of the alloy composition and microstructure limitations recited in claim 1. Because it has been shown above that the Examiner did not meet his burden to establish a *prima facie* case that the invention recited in claim 1 would have been obvious over Smith, it follows that the Examiner's § 103(a) rejection of claim 19 over Smith also should be reversed, and claim 19 should be allowed.

**N.     The § 103(a) Rejection of Claim 20  
         Over Smith should be Reversed**

Claim 20 depends directly from claim 1 and, therefore, incorporates all of the alloy composition and microstructure limitations recited in claim 1. Because it has been shown above that the Examiner did not meet his burden to establish a *prima facie* case that the invention recited in claim 1 would have been obvious over Smith, it follows that the Examiner's § 103(a) rejection of claim 20 over Smith also should be reversed, and claim 20 should be allowed.

**O.     The § 103(a) Rejection of Claim 32  
         Over Smith should be Reversed**

Claim 32 recites an article of manufacture comprising the alloy recited in any of claims 1, 2, 4-8, 10, and 12-20. Each of claims 2, 4-8, 10, and 12-20 depends directly or ultimately from claim 1. Therefore, the "alloy" recited in claim 32 satisfies all of the

composition and microstructure limitations recited in claim 1. Because it has been shown above that the Examiner did not meet his burden to establish a *prima facie* case that the alloy recited in claim 1 would have been obvious over Smith, it follows that the Examiner's § 103(a) rejection of claim 32 over Smith also should be reversed, and claim 32 should be allowed.

**P.     The § 103(a) Rejection of Claim 33  
Over Smith should be Reversed**

Claim 33 is directed to an article of manufacture selected from a list of articles. Claim 33 depends directly from claim 32. Claim 32 recites an article of manufacture comprising the alloy recited in any of claims 1, 2, 4-8, 10, and 12-20. Each of claims 2, 4-8, 10, and 12-20 depends directly or ultimately from claim 1. Therefore, the article of manufacture recited in claim 33 includes an alloy that satisfies all of the composition and microstructure limitations recited in claim 1. Because it has been shown above that the Examiner did not meet his burden to establish a *prima facie* case that the alloy recited in claim 1 would have been obvious over Smith, it follows that the Examiner's § 103(a) rejection of claim 33 over Smith also should be reversed, and claim 33 should be allowed.

**Q.     The § 103(a) Rejection of Claim 34  
Over Smith should be Reversed**

Claim 34 is directed to an article of manufacture selected from two listed articles. Claim 34 depends directly from claim 32. Claim 32 recites an article of manufacture comprising the alloy recited in any of claims 1, 2, 4-8, 10, and 12-20. Each of claims 2, 4-8, 10, and 12-20 depends directly or ultimately from claim 1. Therefore, the article of manufacture recited in claim 34 includes an alloy that satisfies all of the composition and microstructure limitations recited in claim 1. Because it has been shown above that the Examiner did not meet his burden to establish a *prima facie* case that the alloy recited in claim 1 would have been obvious over Smith, it follows that the Examiner's § 103(a) rejection of claim 34 over Smith also should be reversed, and claim 34 should be allowed.

**R.     The § 103(a) Rejection of Claim 53  
Over Smith should be Reversed**

Claim 53 depends directly from claim 1 and, therefore, incorporates all of the alloy composition and microstructure limitations recited in claim 1. Because it has been shown above that the Examiner did not meet his burden to establish a *prima facie* case that the invention recited in claim 1 would have been obvious over Smith, it follows that the Examiner's § 103(a) rejection of claim 53 over Smith also should be reversed, and claim 53 should be allowed.

**S.     The § 103(a) Rejection of Claim 54  
Over Smith should be Reversed**

Claim 54 is directed to an article of manufacture, wherein the article is a wire. Claim 54 depends directly from claim 32. Claim 32 recites an article of manufacture comprising the alloy recited in any of claims 1, 2, 4-8, 10, and 12-20. Each of claims 2, 4-8, 10, and 12-20 depends directly or ultimately from claim 1. Therefore, the article of manufacture recited in claim 54 includes an alloy that satisfies all of the composition and microstructure limitations recited in claim 1. Because it has been shown above that the Examiner did not meet his burden to establish a *prima facie* case that the alloy recited in claim 1 would have been obvious over Smith, it follows that the Examiner's § 103(a) rejection of claim 54 over Smith also should be reversed, and claim 54 should be allowed.

**3.     The Examiner Did Not Establish a *Prima Facie*  
Case Under § 103(a) that Claims 13-15 Would  
Have Been Obvious over Smith as Applied to  
Claim 1, and Further in View of Ototani**

In the Final Office Action (page 8), the Examiner rejects claims 13-15 under § 103(a) as having been obvious over Smith as applied to claim 1, and further in view of Ototani. For the following reasons, Appellant respectfully submits that the Examiner did not satisfy the burden required to establish a *prima facie* case of obviousness over Smith in view of Ototani with respect to any of claims 13-15.

**A. The § 103(a) Rejection of  
Claim 13 Over Smith in view  
of Ototani should be Reversed**

Claim 13 depends directly from claim 1. The “foundation” for this rejection of claim 13 is the above-discussed § 103(a) rejection of claim 1 over Smith. However, it was shown above in Section VII.1.B. that the Examiner did not establish a *prima facie* case that the invention recited in claim 1 would have been obvious over Smith. Therefore, the foundation for the Examiner’s rejection of claim 13 does not exist. For at least that reason, the § 103(a) rejection of claim 13 over Smith in view of Ototani should be reversed, and claim 13 should be allowed.

**B. The § 103(a) Rejection of  
Claim 14 Over Smith in view  
of Ototani should be Reversed**

Claim 14 depends directly from claim 1. The “foundation” for this rejection of claim 14 is the above-discussed § 103(a) rejection of claim 1 over Smith. However, it was shown above in Section VII.1.B. that the Examiner did not establish a *prima facie* case that the invention recited in claim 1 would have been obvious over Smith. Therefore, the foundation for the Examiner’s rejection of claim 14 does not exist. For at least that reason, the § 103(a) rejection of claim 14 over Smith in view of Ototani should be reversed, and claim 14 should be allowed.

**C. The § 103(a) Rejection of  
Claim 15 Over Smith in view  
of Ototani should be Reversed**

Claim 15 depends directly from claim 1. The “foundation” for this rejection of claim 15 is the above-discussed § 103(a) rejection of claim 1 over Smith. However, it was shown above in Section VII.1.B. that the Examiner did not establish a *prima facie* case that the invention recited in claim 1 would have been obvious over Smith. Therefore, the foundation for the Examiner’s rejection of claim 15 does not exist. For at least that reason, the § 103(a) rejection of claim 15 over Smith in view of Ototani should be reversed, and claim 15 should be allowed.

**4. The Examiner Did Not Establish a *Prima Facie* Case Under § 103(a) that Claims 20, 32-34, and 54 Would have been Obvious over Smith as Applied to Claim 1, and Further in View of Thompson**

In the Final Office Action (page 9), the Examiner rejects claims 20, 32-34, and 54 under § 103(a) as having been obvious over Smith as applied to claim 1, and further in view of Thompson. Appellant respectfully submits that the Examiner did not satisfy the burden required to establish a *prima facie* case of obviousness of any of claims 20, 32-34, and 54 over Smith in view of Thompson.

**A. The § 103(a) Rejection of Claim 20 Over Smith in view of Thompson Should be Reversed**

Claim 20 depends directly from claim 1. The “foundation” for this rejection of claim 20 is the above-discussed § 103(a) rejection of claim 1 over Smith. However, it was shown above that the Examiner did not establish a *prima facie* case that the invention recited in claim 1 would have been obvious over Smith. Therefore, the foundation for the Examiner’s rejection of claim 20 does not exist. For at least that reason, the § 103(a) rejection of claim 20 over Smith in view of Ototani should be reversed, and claim 20 should be allowed.

**B. The § 103(a) Rejection of Claim 32 Over Smith in view of Thompson should be Reversed**

Claim 32 recites an article of manufacture comprising the alloy recited in any of claims 1, 2, 4-8, 10, and 12-20. Each of claims 2, 4-8, 10, and 12-20 depends directly or ultimately from claim 1. Therefore, the “alloy” recited in claim 32 satisfies all of the composition and microstructure limitations recited in claim 1. Because it has been shown above that the Examiner did not meet his burden to establish a *prima facie* case that the alloy recited in claim 1 would have been obvious over Smith, it follows that the Examiner’s § 103(a) rejection of claim 32 over Smith in view of Thompson also should be reversed, and claim 32 should be allowed.



**C. The § 103(a) Rejection of  
Claim 33 Over Smith in view  
of Thompson Should be Reversed**

Claim 33 is directed to an article of manufacture selected from a list of articles. Claim 33 depends directly from claim 32. Claim 32 recites an article of manufacture comprising the alloy recited in any of claims 1, 2, 4-8, 10, and 12-20. Each of claims 2, 4-8, 10, and 12-20 depends directly or ultimately from claim 1. Therefore, the article of manufacture recited in claim 33 includes an alloy that satisfies all of the composition and microstructure limitations recited in claim 1. Because it has been shown above that the Examiner did not meet his burden to establish a *prima facie* case that the alloy recited in claim 1 would have been obvious over Smith, it follows that the Examiner's § 103(a) rejection of claim 33 over Smith in view of Thompson also should be reversed, and claim 33 should be allowed.

**D. The § 103(a) Rejection of  
Claim 34 Over Smith in view  
of Thompson Should be Reversed**

Claim 34 is directed to an article of manufacture selected from two listed articles. Claim 34 depends directly from claim 32. Claim 32 recites an article of manufacture comprising the alloy recited in any of claims 1, 2, 4-8, 10, and 12-20. Each of claims 2, 4-8, 10, and 12-20 depends directly or ultimately from claim 1. Therefore, the article of manufacture recited in claim 34 includes an alloy that satisfies all of the composition and microstructure limitations recited in claim 1. Because it has been shown above that the Examiner did not meet his burden to establish a *prima facie* case that the alloy recited in claim 1 would have been obvious over Smith, it follows that the Examiner's § 103(a) rejection of claim 34 over Smith in view of Thompson also should be reversed, and claim 34 should be allowed.

**E. The § 103(a) Rejection of  
Claim 53 Over Smith in view  
of Thompson should be Reversed**

Claim 53 depends directly from claim 1 and, therefore, incorporates all of the alloy composition and microstructure limitations recited in claim 1. Because it has been shown above that the Examiner did not meet his burden to establish a *prima facie* case that the invention recited in claim 1 would have been obvious over Smith, it follows that the Examiner's § 103(a) rejection of claim 53 over Smith in view of Thompson also should be reversed, and claim 53 should be allowed.

**F. The § 103(a) Rejection of  
Claim 54 Over Smith in view  
of Thompson should be Reversed**

Claim 54 is directed to an article of manufacture, wherein the article is a wire. Claim 54 depends directly from claim 32. Claim 32 recites an article of manufacture comprising the alloy recited in any of claims 1, 2, 4-8, 10, and 12-20. Each of claims 2, 4-8, 10, and 12-20 depends directly or ultimately from claim 1. Therefore, the article of manufacture recited in claim 54 includes an alloy that satisfies all of the composition and microstructure limitations recited in claim 1. Because it has been shown above that the Examiner did not meet his burden to establish a *prima facie* case that the alloy recited in claim 1 would have been obvious over Smith, it follows that the Examiner's § 103(a) rejection of claim 54 over Smith in view of Thompson also should be reversed, and claim 54 should be allowed.

**D. Any *Prima Facie* Case Under § 103(a) that  
the Examiner Did Establish Was Rebutted by  
the Evidence of Secondary Considerations**

Even if the Examiner did establish a *prima facie* case of obviousness of any of the claims based on Smith, Smith in view of Ototani, or Smith in view of Thompson, Applicants submitted evidence of secondary considerations that effectively rebutted any such *prima facie* case and clearly established that the invention recited in claim 1 was not obvious on a date just before the Present Application was filed.

MPEP § 2144.05 explains that the nonobviousness of overlapping ranges can be established by a showing that the claimed invention addresses a long-felt and unmet need, provides unexpected results, and/or has met with commercial success. Each of these three secondary considerations was established here. Specifically, Applicants submitted the Lippard Declaration and the Myers Declaration, as well as other evidence, showing that the claimed invention: (1) addressed a long-felt and unmet need; (2) provided unexpected results; and (3) met with substantial commercial success. Appellant addresses each of type of evidence and the Examiner's relevant arguments below.

**1. Applicants Submitted Evidence  
Showing that the Claimed Invention  
Satisfied a Long-Felt and Unmet Need**

As discussed in Section VII.1.A. of this Appeal Brief and in the Lippard Declaration (attached as Exhibit 1), the alloy recited in claim 1 of the Present Application addressed a long-felt need that was unmet before the invention recited in claim 1 was made by the present inventors. In particular, a need existed for a new MP35N-type alloy having substantially improved fatigue resistance over conventional MP35N alloy and that could be formed into small-diameter alloy wire for use in cardiac pacemaker leads and other surgical implants. The urgent nature of this need is evident given that cardiac pacemaker leads and other surgical implants formed from conventional MP35N alloy are implanted in the human body. Improved fatigue

resistance is an especially important objective in cardiac pacemaker leads, which are fabricated from small diameter MP35N wire. An end of the lead is inserted into the heart muscle and conducts current from the pacemaker to the heart to continuously regulate the heartbeat. Fracture of an implanted pacemaker lead can have severe consequences. Therefore, it was considered especially important to increase pacemaker lead service lifetime in order to postpone replacement surgery. Nevertheless, despite the importance of the long-standing objective of increasing fatigue properties of MP35N-type alloy for these applications, that objective was not met until the present inventors conceived of the alloy recited in claim 1.

In the Final Office Action (page 12), the Examiner takes issue with the evidence of long-felt need. However, in contrast to the Examiner's assertions in the Final Office Action, the evidence of long felt and unmet need submitted in the Present Application, which is discussed in above Section VII.1.A. and in the Lippard Declaration, does show that the need was recognized, persistent, and had not been solved by others. Moreover, the alloy recited in claim 1 has been shown to address the need by providing substantially improved fatigue resistance in, for example, small-diameter wire form. See MPEP § 716.04. There exists no evidence or suggestion that the failure of others to solve the long-felt need was not due to lack of interest or lack of appreciation of an invention's potential or marketability. *Id.*

The evidence of long-felt and unmet need submitted to the Examiner establishes that the alloy composition recited in claim 1 of the Present Application was not obvious. Because the alloy composition recited in claim 1 is incorporated into each of rejected claims 2, 4-8, 10, 12-20, 32-34, 53, and 54, it follows that the subject matter of each such claim also would not have been obvious for the same reasons. Accordingly, the evidence submitted to the Examiner that the claimed invention satisfied a long-felt and unmet need rebuts any *prima facie* case of obviousness of the claims that the Examiner may have established in the Final Office Action. Therefore, if it is determined that the Examiner did establish a *prima facie* case that the inventions of any of claims 1, 2, 4-8, 10, 12-20, 32-34, 53, and 54 would have been obvious, then those rejections should be reversed and those claims should be allowed.

**2. Applicants Submitted Evidence  
Showing that the Claimed Invention  
Provided Surprising and Unexpected Results**

The Present Application includes evidence that the fatigue properties of wire formed from the alloy recited in claim 1 are substantially improved over wire formed from conventional MP35N alloy. Also, during prosecution of the Present Application, Applicants submitted the Lippard Declaration (attached as Exhibit 1), providing detailed and uncontradicted evidence of unexpected results. The Examiner, however, apparently discounts the pertinence of this uncontradicted evidence for reasons that cannot be determined clearly from the record and cannot be sustained.

In the Final Office, the Examiner does not clearly address the evidence of surprising and unexpected results submitted by Applicants. Instead, in the Final Office Action (page 10) the Examiner simply states that "... Applicant has failed to show that this range [less than 30 ppm nitrogen] would provide unexpected results over the prior art range of 0 to 500 ppm." However, as discussed above in Section VII.1.B. of this Appeal Brief and in the Lippard Declaration (attached as Exhibit 1), Smith does not teach a range of 0 to 500 ppm nitrogen to one having ordinary skill. Instead, Smith teaches an alloy that includes no more than 500 ppm nitrogen and which would have included no less than the conventional minimum level of 50 ppm nitrogen. As discussed above, Smith does not disclose or in any way suggest an alloy including the very low levels of nitrogen, less than 30 ppm, that are critical to the fatigue performance of the alloy recited in claim 1. Nor does Smith teach or suggest any reason to undertake the expense of limiting nitrogen in the alloy to the extremely low levels of the alloy claimed in the Present Application. Therefore, the Examiner's conclusion that Applicants did not show "unexpected results over the prior art range of 0 to 500 ppm" is fundamentally flawed given that Smith does not teach a range of 0 to 500 ppm nitrogen. For that reason alone, the Examiner's failure to accept that the evidence of unexpected results establishes nonobviousness must be reversed and the pending claims should be passed to allowance.

More broadly, In the Final Office Action the Examiner has not provided any rationale providing sufficient support for his apparent position that the evidence submitted in the Present Application does not prove the existence of unexpected results. As noted, the Examiner simply states that "... Applicant has failed to show that this range [less than 30 ppm nitrogen] would provide unexpected results over the prior art range of 0 to 500 ppm." Clearly, such a brief and non-specific treatment of this evidence is insufficient for purposes of an Office Action. See, e.g., *In re Kahn*, 441 F.3d at 988 ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."); see also *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983) ("Evidence rising out of the so-called 'secondary considerations' must always when present be considered en route to a determination of obviousness.").

The Present Application includes unambiguous comparative data showing that small diameter wire formed of the claimed alloy is substantially more fatigue resistant than wire formed from conventional MP35N alloy. This data is presented in Table 9 and the accompanying text in the Present Application. As also discussed in the Lippard Declaration (Exhibit 1), small-diameter wire formed from the alloy recited in claim 1 has a unique and unexpectedly well-tolerated microstructure that provides unexpectedly and substantially improved fatigue properties relative to conventional MP35N wire. On these issues, the uncontradicted statements in the Lippard Declaration are as follows:

9. In an attempt to address the observed microstructural deficiencies in MP35N alloy, we experimented with modifications to the chemistry of conventional MP35N alloy. We surprisingly discovered that modifying the existing alloy chemistry to limit nitrogen to extremely low levels, less than 30 ppm, reducing titanium to less than 0.7 weight percent, and including certain small concentrations of at least one of aluminum, calcium, magnesium, or cerium resulted in an alloy with a fundamentally different microstructure – the microstructure substantially lacked cuboidal titanium nitride and mixed metal carbonitride inclusions and, instead, included relatively small, generally spherical oxide inclusions. We observed that the relatively small, generally rounded oxide inclusions are well tolerated by (*i.e.*, would not

heavily score) the wire drawing equipment, substantially reducing the incidence of wire surface defects, and are much less likely to concentrate stresses in the wire to a degree resulting in wire fracture during drawing or when subjected to fatigue over time.

10. The very substantial change in microstructure produced by the chemistry modifications we made was entirely unexpected and very significant. The change was not merely a slight adjustment to microstructure, but unexpectedly resulted in a fundamentally different and well tolerated microstructure. Fortunately, the new microstructure of the alloy directly addressed the microstructural problems in the conventional MP35N alloy.

11. As discussed in detail in the Application, an apparent result of the ... fundamentally different microstructure of the small-diameter wire produced from the alloy described in the Application [is that the alloy] exhibits very substantially improved fatigue resistance relative to conventional MP35N alloy. Table 9 of the Application, for example, shows that at 100 ksi, a stress level similar to that to which cardiac pacemaker leads are subjected in service (*i.e.*, implanted in the body), wire formed from the alloy described in the Application withstood at least 797% the number of cycles in rotary beam fatigue testing than wire produced from conventional MP35N alloy, and the modified alloy had a fatigue endurance limit of between 100-110 ksi versus the 90 ksi limit of the conventional alloy. This improvement in fatigue properties was very significant, was surprising to me and my co-inventors, and was not expected even after we observed the fundamentally altered microstructure of the alloy of the Application. ...

In prior Office Actions issued in the Present Application, the Examiner did not take issue with the type of comparative testing or the number of test samples included in the Applicants' evidence of unexpected results. In the Final Office Action (page 10) the Examiner states without elaboration that "[t]o establish unexpected results over a claimed range, the Applicant should compare a sufficient number of tests both inside and outside the claimed range to show the criticality of the claimed range." This bald statement merely parrots MPEP § 716.02(d)(II) and does not appear to be a separate basis for concluding that the showing of unexpected results is insufficient – for example, the Examiner does not directly address the character of the comparative testing completed or the number of tests that were presented as evidence of unexpected

results. As stated in MPEP § 716.01(a), "Examiners must consider comparative data in the specification which is intended to illustrate the claimed invention in reaching a conclusion with regard to the obviousness of the claims." Instead, the sole rationale included in the Final Office Action as to why the Examiner apparently discounts the evidence of unexpected results is that the Applicant "failed to show that this range [less than 30 ppm nitrogen] would provide unexpected results over the prior art range of 0 to 500 ppm." As shown above, however, this rationale is flawed because it mischaracterizes what is taught by the cited prior art (Smith).

In the November 30, 2007 Office Action, the Examiner argued that the Lippard Declaration's evidence of surprising and unexpected results is not suitably tied to the subject matter recited in the claims under examination because "the scope of independent claims 1 and 53 are directed to an alloy and not a wire and the scope of the dependent claims do not limit the scope of the alloy to a wire." (See the November 30, 2007 Office Action at page 9, lines 8-16.) In other words, when the Examiner directly addressed the evidence Applicants presented of surprising and unexpected results in the November 30, 2007 Office Action, the Examiner did not contend that the evidence fails to show an unexpected and unobvious result, or a result that lacks practical significance. Instead, the Examiner apparently argued that a comparison of the fatigue properties of alloys formed into wires does not establish that properties of the alloys significantly differ. Although the Examiner did not repeat this argument in the Final Office Action in connection with the showing of unexpected results, it is unclear whether or not this basis for discounting the unexpected results evidence has been laid to rest once and for all. Therefore, Appellant addresses it in the following paragraphs.

The improved fatigue resistance of the claimed alloy is a function of the alloy's composition and microstructure – it is not a result of the process of forming the alloy into a small-diameter wire. If the unexpected fatigue resistance were related to the process of drawing the alloy into wire, then the conventional MP35N wire would have exhibited substantially the same fatigue resistance as the experimental wire. Instead, because the alloy claimed in the Present Application and the conventional MP35N alloy were formed into wire in the same way and were tested in the same way, effectively



canceling out any influence of the wire forming process, it necessarily follows that the improvement in fatigue resistance is attributable to the differences between the alloys.

The essence of a meaningful comparison of properties is that the inventive alloy and the closest prior art alloy were evaluated under identical conditions, which is what occurred here – small-gauge wire formed from conventional MP35N alloy was compared with small-gauge wire formed from the alloy recited in claim 1. If, for example, the tensile strength of the conventional and claimed alloys were compared, then an identical tensile test specimen would have been machined from each alloy and tested on the particular tensile testing machine under identical conditions. The alloy, however, would be used commercially to make articles of manufacture (wire, for example) and not tensile test specimens. Nevertheless, the Patent Office does not require that the claims under examination recite “a tensile test specimen” consisting of the inventive alloy in order to tie the showing of unexpected results to the claimed invention. Alternatively, if salt water corrosion resistance of the conventional and claimed alloys had been compared to establish unexpected results, then an identical corrosion test specimen (a square coupon, for example) would have been prepared from each alloy, the specimens would have been subjected to an identical salt water solution under identical test conditions, and corrosion performance would have been observed over time. Nevertheless, the Patent Office would not require that the claims under examination recite “a corrosion test specimen” consisting of the inventive alloy in order to properly tie the unexpected results to the claimed invention. It is common practice, and is more meaningful to assessing patentability, to evaluate the properties of alloy specimens under real-life conditions when considering whether an unexpected improvement is provided in mechanical properties. Here, Applicants supplied the most meaningful evidence of the alloy's unexpected and surprising properties that could be fashioned – the inventors investigated the long-term fatigue performance of the alloy of the invention relative to that of conventional MP35N alloy (the closest prior art) by drawing the alloys to small-diameter wire form and testing the wire samples under conditions simulating a real-life environment in which the alloys are used.

Therefore, any position that the claims must be directed to "a wire" composed of the inventive alloy cannot be sustained. The compelling evidence of unexpected and surprising improvement in fatigue performance clearly relates to the alloy and effectively rebuts any *prima facie* case of obviousness that the Examiner may have established.

In addition, Applicants note that Paragraphs 9 and 10 of the Lippard Declaration, quoted above, explain that the alloy claimed in the Present Application had an entirely unexpected, surprising, and particularly advantageous microstructure. That microstructure directly addressed certain microstructural deficiencies in conventional MP35N alloy. The unexpected, surprising, and advantageous microstructure of the alloy recited in claim 1 is a property of the alloy. This evidence of an unexpected and surprising change in a fundamental characteristic of the alloy recited in claim 1 relative to conventional MP35N alloy effectively rebuts any *prima facie* obviousness case that the Examiner may have established. See, e.g., *In re Waymouth*, 499 F.2d 1273, 1276 (CCPA 1974) ("In order to show an unexpected result, we do not believe that the lamp must be inoperable over other ranges, but rather that over the claimed critical range, there be a difference in kind, rather than in degree.").

In sum, the evidence of surprising and unexpected results submitted to the Examiner establishes that the alloy composition recited in claim 1 of the Present Application was not obvious. Because the alloy composition recited in claim 1 is incorporated into each of rejected claims 2, 4-8, 10, 12-20, 32-34, 53, and 54, it follows that the subject matter of each such claim also would not have been obvious for the same reasons. Therefore, the evidence submitted to the Examiner that the claimed invention provided surprising and unexpected microstructure and mechanical properties rebutted any *prima facie* case of obviousness of the claims that the Examiner may have established in the Final Office Action. Therefore, for this reason the § 103(a) rejections of claims 1, 2, 4-8, 10, 12-20, 32-34, 53, and 54 should be reversed and those claims should be allowed.

**3. Applicants Submitted Evidence  
Showing that the Claimed Invention  
Achieved Commercial Success**

Applicants submitted the Myers Declaration (attached as Exhibit 2) to show that (1) small diameter wire produced from the alloy recited in claim 1 has enjoyed very substantial commercial success and (2) the commercial success is directly attributable to the unexpectedly and substantially improved fatigue resistance of the alloy. In the Final Office Action, the Examiner does not argue that the Myers Declaration fails to show a substantial increase in sales of wire produced from the alloy recited in the claims. Instead, the Examiner takes other positions in the Final Office Action, which we address in the following paragraphs.

**a. The Evidence of Commercial Success  
is Commensurate in Scope with Claim 1**

The Myers Declaration details sales of small diameter 35N LT<sup>®</sup> wire made from the alloy of claim 1. In the Final Office Action (page 12), the Examiner asserts that the evidence presented in the Myers Declaration is “not commensurate in scope” with the claims because the declaration is directed to wire, while the independent claims are “directed toward merely an alloy composition.” Appellant disagrees with this basis for discounting the evidence in the Myers Declaration and requests that it be reversed.

Objective evidence of commercial success is not commensurate with the claims if the claims are broader than the scope of the objective evidence. *Joy Technologies, Inc. v. Manbeck*, 751 F.Supp. 225, 229 (D.D.C. 1990), *aff’d*, 959 F.2d 226 (Fed. Cir. 1992). The claims are broader in scope than the objective evidence if a limitation or element recited in the claim is broader than the limitation or element in the objective evidence. *Id.* Claim 1 of the Present Application is directed to an “alloy”. Here, the contradicted evidence is that the alloy from which the wire discussed in the Myers Declaration was formed had a composition and microstructure satisfying each and every element and limitation recited in claim 1 of the Present Application. On that point, paragraph 6 of the Myers Declaration states as follows:

6. Since 2003, FWM has purchased rods and coils of a particular cobalt-nickel-chromium-molybdenum alloy from ATI Allvac having a chemistry and microstructure that falls squarely within at least Claim 1 of the Application. Specifically, the ATI Allvac alloy has the chemistry and microstructure recited in the current form of the Application's Claim 1. FWM processes the ATI Allvac alloy into small diameter wire of several diameters, and markets and sells the small diameter wire as 35N LT® wire for use in surgical implant products. Medical device companies purchase FWM's 35N LT wire for use in a number of surgical implant applications, including cardiac pacemaker and defibrillator leads and styles, catheters, orthopedic cables, and stents.

The small diameter 35N LT® wire that is discussed in the Myers Declaration clearly is an "alloy". Also, the uncontradicted evidence of record, based on the Myers Declaration, is that the wire had a chemistry and a microstructure satisfying all of the limitations recited in claim 1.<sup>2</sup> Accordingly, the evidence supplied by the Myers Declaration is commensurate in scope with the claims under examination, and this basis for discounting the evidence of commercial success should be reversed.<sup>3</sup>

**b.     A Nexus Has Been Shown to Exist  
       Between Sales and the Claimed Invention**

In the Final Office Action (page 13), the Examiner states the following regarding the evidence of commercial success submitted in the Myers Declaration:

... Applicant's opinion as to the purchaser's reason for buying the product is insufficient to demonstrate a nexus between the sales and the claimed invention; the Applicant has not shown whether or not the sales of the 35N LT wire were based on heavy promotion or advertising, shift in advertising, consumption by

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<sup>2</sup> Appellant wonders exactly what evidence of commercial success the Examiner would consider "commensurate in scope" with claims directed to an "alloy". Obviously, an alloy must exist in some form such as, for example, a sheet, a strip, an ingot, a billet, a bar, a rod, or a wire. All such forms, however, consist of "alloy".

<sup>3</sup> Appellant notes that the Examiner's arguments regarding whether the evidence is "commensurate in scope" with the claims apparently is limited to the "independent claims". However, independent claim 32 is directed to "an article of manufacture"; dependent claims 33 and 34 are directed to articles including "a wire"; and dependent claim 54 is directed specifically to "a wire".

purchasers normally tied to applicant or assignee, or other business events extraneous to the merits of the instant invention....

Appellant respectfully submits that a sufficient nexus between the evidence of commercial success and the merits of the claimed invention was established and that the Examiner has no reasonable basis for refusing to accept that the evidence confirms the non-obvious character of the claimed invention. The Myers Declaration includes the following pertinent paragraphs:

6. Since 2003, [Fort Wayne Metals] has purchased rods and coils of a particular cobalt-nickel-chromium-molybdenum alloy from ATI Allvac having a chemistry and microstructure that falls squarely within at least Claim 1 of the Application. Specifically, the ATI Allvac alloy has the chemistry and microstructure recited in the current form of the Application's Claim 1. FWM processes the ATI Allvac alloy into small diameter wire of several diameters, and markets and sells the small diameter wire as 35N LT® wire for use in surgical implant products. Medical device companies purchase FWM's 35N LT wire for use in a number of surgical implant applications, including cardiac pacemaker and defibrillator leads and stylets, catheters, orthopedic cables, and stents.

\* \* \* \*

11. The substantial commercial success that FWM has had with 35N LT wire is directly attributable to its substantially improved fatigue resistance relative to other alloys suitable for use in surgical implant applications. As manufacturers of pacemaker leads and related products have become familiar with the significantly improved fatigue resistance of 35N LT wire, they increasingly prefer the product over other available wire products suitable for their applications. I do not base this conclusion only on the substantial, rapid, and continuing increase in FWM's sales of 35N LT wire and on the fact that 35N LT wire has largely displaced other available biocompatible alloys for use in several surgical implant applications. I also base this conclusion on direct feedback from customers for 35N LT wire for use in certain surgical implant applications – those customers state that they chose FWM's 35N LT wire over wire formed from other available alloys because of the FWM product's superior fatigue resistance.

The evidence provided in these paragraphs, which is based on Mr. Myers' direct knowledge of sales of the 35N LT wire product and direct feedback from customers for

the wire, is compelling – customers of FWM directly told Mr. Myers that they chose the product based on its “superior fatigue resistance”, rather than for other reasons. Such a statement is not Mr. Myers’ opinion, but rather is direct evidence, as told to Mr. Myers by the customers themselves, that the customer’s orders for 35N LT wire were motivated by the product’s superior fatigue properties. What could be more focused and compelling on the issue of why the customers purchased the product than a declaration from a knowledgeable person who had spoken with customers who purchased the product? The Myers Declaration constitutes factual evidence on the issue of the purchasers’ motivation. See MPEP 716.02(g) (“The reason for requiring evidence in declaration or affidavit form is to obtain the assurances that any statements or representations made are correct, as provided by 35 U.S.C. 25 and 18 U.S.C. 1001.”) That evidence must be accepted unless there is reason to consider it false.

The above-quoted paragraphs from the Myers Declaration are based on Mr. Myer’s first-hand knowledge of the market for and consumers of conventional MP35N wire and his company’s 35N LT<sup>®</sup> wire for use in pacemaker leads and related products. For example, paragraph 5 of Mr. Myer’s declaration explains that he is “responsible for business development and all commercial activity within” Fort Wayne Metals (FWM). Further, paragraph 7 states that Mr. Myers is:

thoroughly familiar with the quantities of 35N LT wire FWM has sold and the gross revenues for such sales, and I routinely interact with FWM’s customers for the product and request and obtain comments from those customers about their experiences using the product.

Thus, Mr. Myers directly interacted with FWM’s customers for 35N LT wire and obtained their first-hand comments regarding the product. Given Mr. Myer’s direct and informed knowledge as to why FWM’s customers purchased 35N LT wire, his above-quoted observation in declaration paragraph 7 is not an opinion, but rather is direct evidence of FWM’s customers’ preferences and that they “increasingly prefer the product over other available wire products suitable for their applications.”

Moreover, the sales figures listed in the table and illustrated in the figures of the Myers Declaration are factual evidence confirming Mr. Myer’s statement that FWM’s

customers “increasingly prefer the [35N LT] product over other available wire products suitable for their applications.” As noted in the Myers Declaration, FWM filled its first commercial order for 35N LT wire in June of 2003, and in the second half 2003 filled 15 orders for 35N LT wire for a total of about 357,000 linear feet. Filled orders more than quadrupled in 2004, during which FWM shipped over 19 million feet of 35N LT wire. During 2005, the number of orders was 170% of the 2004 figure, and the total length of wire shipped, just over 55 million linear feet, was about 280% of the 2004 length. In 2006, orders increased to 150% and total linear feet shipped advanced to 190% of the prior year’s figures. These large increases in sales of 35N LT wire are not the result of like increases over the period in the numbers of surgical implant procedures performed using small diameter MP35N-type wire – instead, the substantial increases undeniably reflect an increased consumer preference for the FWM wire product made from the alloy of the Present Application.

The evidence of commercial success submitted to the Examiner establishes that the alloy composition recited in claim 1 of the Present Application was not obvious. Because the alloy composition recited in claim 1 is incorporated into each of rejected claims 2, 4-8, 10, 12-20, 32-34, 53, and 54, it follows that the subject matter of each such claim also would not have been obvious for the same reasons. Therefore, the evidence submitted to the Examiner that the claimed invention provided surprising and unexpected microstructure and mechanical properties rebutted any *prima facie* case of obviousness of the claims that the Examiner may have established in the Final Office Action. Therefore, for this reason the § 103(a) rejections of claims 1, 2, 4-8, 10, 12-20, 32-34, 53, and 54 should be reversed and those claims should be allowed.

**VIII. CLAIMS APPENDIX**

1. An alloy having favorable fatigue resistance and comprising:
  - at least 20 weight percent cobalt;
  - 32.7 to 37.3 weight percent nickel;
  - 18.75 to 21.25 weight percent chromium;
  - 8.85 to 10.65 weight percent molybdenum; and
  - less than 30 ppm nitrogen;
  - less than 0.7 weight percent titanium;
  - at least one of at least 0.05 to 0.15 weight percent aluminum, at least 5 to 20 ppm calcium, at least 5 to 50 ppm magnesium, and at least 5 to 50 ppm cerium; and
  - no greater than 1.05 weight percent iron;
  - no greater than 0.035 weight percent carbon; andwherein the alloy includes generally spherical oxide inclusions and is substantially free of titanium nitride and mixed metal carbonitride inclusions.
2. The alloy of claim 1, comprising less than 20 ppm nitrogen.
3. (cancelled)
4. The alloy of claim 1, further comprising less than 0.03 weight percent titanium.
5. The alloy of claim 1, further comprising:
  - no greater than 0.18 weight percent manganese;
  - no greater than 0.17 weight percent silicon;
  - no greater than 0.020 weight percent phosphorus;



- no greater than 0.015 weight percent sulfur; and
- no greater than 0.020 weight percent boron.
6. The alloy of claim 1, comprising:
- 33.0 to 37.0 weight percent nickel;
- 19.0 to 21.0 weight percent chromium; and
- 9.0 to 10.5 weight percent molybdenum.
7. The alloy of claim 6, further comprising:
- no greater than 0.025 weight percent carbon;
- no greater than 0.15 weight percent manganese;
- no greater than 0.15 weight percent silicon;
- no greater than 0.015 weight percent phosphorus;
- no greater than 0.010 weight percent sulfur;
- no greater than 1.0 weight percent iron; and
- no greater than 0.015 weight percent boron.
8. The alloy of claim 7, comprising less than 20 ppm nitrogen.
9. (cancelled)
10. The alloy of claim 7, further comprising less than 0.03 weight percent titanium.
11. (cancelled)
12. The alloy of claim 1, comprising 0.05 to 0.15 weight percent aluminum.

13. The alloy of claim 1, comprising 5 to 20 ppm calcium.
14. The alloy of claim 1, comprising 5 to 50 ppm calcium.
15. The alloy of claim 1, comprising 5 to 50 ppm cerium.
16. The alloy of claim 1, wherein the alloy does not exhibit significant oxygen embrittlement at grain boundaries.
17. The alloy of claim 1, wherein the alloy is substantially free of titanium.
18. The alloy of claim 1, wherein the alloy is substantially free of nitrogen.
19. The alloy of claim 1, wherein the alloy has an endurance limit greater than 100 ksi.
20. The alloy of claim 1, wherein the alloy qualifies for use in surgical implant applications under ASTM standard specification F 562.
- 21-31. (cancelled)
32. An article of manufacture comprising the alloy of any of claims 1, 2, 4-8, 10, and 12-20.
33. The article of manufacture of claim 32, wherein the article of manufacture is selected from a bar, a wire, a tube, a surgical implant device, a component for a surgical implant device, an implantable defibrillator, a component for an implantable defibrillator,

an implantable pacemaker, a component for an implantable pacemaker, a pacing lead, and a cardiac stent.

34. The article of manufacture of claim 32, wherein the article of manufacture is one of a bar and a wire, and qualifies for use in surgical implant applications under ASTM standard specification F 562.

35-52. (cancelled)

53. The alloy of claim 1, consisting of:

at least 20 weight percent cobalt;

32.7 to 37.3 weight percent nickel;

18.75 to 21.25 weight percent chromium;

8.85 to 10.65 weight percent molybdenum;

less than 30 ppm nitrogen;

less than 0.7 weight percent titanium;

at least one of at least 0.05 to 0.15 weight percent aluminum, at least 5 to 20 ppm calcium, at least 5 to 50 ppm magnesium, and at least 5 to 50 ppm cerium;

no greater than 1.05 weight percent iron;

no greater than 0.035 weight percent carbon;

no greater than 0.18 weight percent manganese;

no greater than 0.17 weight percent silicon;

no greater than 0.020 weight percent phosphorus;

no greater than 0.015 weight percent sulfur;

no greater than 0.020 weight percent boron; and

incidental impurities,

wherein the alloy includes generally spherical oxide inclusions and is substantially free of titanium nitride and mixed metal carbonitride inclusions.

54. The article of manufacture of claim 32, wherein the article of manufacture is a wire.

**IX. EVIDENCE APPENDIX**

The content of this Evidence Appendix includes the following:

- a copy of the "Declaration of Henry E. Lippard, Ph.D.", signed August 24, 2007, is attached as Exhibit 1
- a copy of the "Declaration of Robert J. Myers", dated September 7, 2007, is attached as Exhibit 2

X. **RELATED PROCEEDINGS AND APPENDIX**

None

**XI. CONCLUSION**

For the reasons discussed above, Appellant respectfully submits that the Examiner has not established a *prima facie* case of obviousness as applied to any of the pending claims. Moreover, even if such a case was established, Appellant respectfully submits that the evidence of secondary considerations submitted to the Examiner was sufficient to rebut any established case of obviousness.

Accordingly, Appellant respectfully requests that the Examiner be directed to: (1) reverse the § 103(a) rejection of 1, 2, 4-8, 10, 12, 16-20, 32-34, 53, and 54 over Smith; (2) reverse the § 103(a) rejection of claims 13-15 over Smith as applied to claim 1, and further in view of Ototani; (3) reverse the § 103(a) rejection of claims 20, 32-34, and 54 over Smith as applied to claim 1, and further in view of Thompson; and (4) allow all claims currently ending in the Present Application.

Respectfully submitted,

July 2, 2009  
Date

Mark R. Leslie  
Mark R. Leslie  
Reg. No. 36,360

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## **EXHIBIT 1**



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of Forbes Jones et al.	:	
	:	COBALT-NICKEL-CHROMIUM-
Group Art Unit 1742	:	MOLYBDENUM ALLOYS WITH
	:	REDUCED LEVEL OF TITANIUM
Serial No. 10/656,918	:	NITRIDE INCLUSIONS
	:	
Filed September 5, 2003	:	
	:	Confirmation No. 8375
Examiner Jessee Roe	:	

DECLARATION OF HENRY E. LIPPARD, Ph.D.

Pittsburgh, Pennsylvania 15222-2312  
August 23, 2007

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

1. I, Henry E. Lippard, declare as follows:
2. I am a citizen of the United States and currently reside at 9810 Edinburgh Lane, Charlotte, North Carolina.
3. I am over the age of eighteen and am competent to make the statements in this Declaration.
4. I obtained my Bachelor of Science in Materials Science and Engineering from North Carolina State University in 1992, and my Ph.D. in Materials Science and Engineering from Northwestern University in 1999.
5. I have been employed by ATI Allvac, a business unit of Allegheny Technologies Incorporated, located in Monroe, North Carolina, since July, 1997. My current position with ATI Allvac is Manager – Raw Materials and Nickel-base Primary Melting. Through my educational background and my employment at ATI Allvac I have

gained substantial experience and familiarity with alloy melting and other alloy preparation techniques including techniques for influencing alloy microstructure and properties. I have particular experience in the preparation of nickel-base alloys and other high performance non-ferrous alloys.

6. I am named as an inventor on the above-identified U.S. patent application ("the Application"). I am thoroughly familiar with the Application and the claims currently pending in the Application as amended in the Response accompanying this declaration. I also am thoroughly familiar with the alloy described in the Application and, in particular, am thoroughly familiar with a commercially available embodiment of the alloy described in the Application, which is sold by my employer, ATI Allvac.

#### **The History of the Invention Described in the Application**

7. Prior to the invention of the alloy described in the Application, a need existed for many years for biocompatible small diameter MP35N-type alloy wire having improved fatigue resistance. Cardiac pacemaker and defibrillator leads and certain other components of surgically implanted medical devices are commonly made from small diameter MP35N alloy wire. A known problem with MP35N alloy is that surface defects appear on wire drawn from the alloy. These surface defects tend to appear late in the wire production process, after substantial time and money has been invested in the product. The surface defects may cause the wire to fracture during the drawing process, which resulted in reduced product yield and increased the commercial cost of the wire. Also, pacemaker leads and certain other surgically implanted components formed from MP35N alloy wire having the surface defects were susceptible to fracture from fatigue, reducing in-service life and requiring premature replacement of the implant.

8. My co-inventors and I ("we") undertook to address these problems. In the course of this research we discovered that generally large, cuboidal titanium nitride and mixed metal carbonitride inclusions present in conventional MP35N alloy were scoring the surfaces of drawing dies used to draw the alloy to small-diameter wire. We further discovered that the surface defects discussed above were formed when wire is drawn through dies damaged by the inclusions. The surface defects manifested as scratches

on the wire surface that can hasten fatigue-induced fracture of the wire. We also discovered that as the wire diameter becomes smaller during drawing, nitride and carbonitride particles occupied an increasingly larger fraction of the wire cross-section, thereby weakening the wire and resulting in fractures during drawing. We further discovered that the cuboidal inclusions act as points of localized stress during fatigue loading and contribute to fatigue crack initiation, which can result in premature wire failure.

9. In an attempt to address the observed microstructural deficiencies in MP35N alloy, we experimented with modifications to the chemistry of conventional MP35N alloy. We surprisingly discovered that modifying the existing alloy chemistry to limit nitrogen to extremely low levels, less than 30 ppm, reducing titanium to less than 0.7 weight percent, and including certain small concentrations of at least one of aluminum, calcium, magnesium, or cerium resulted in an alloy with a fundamentally different microstructure – the microstructure substantially lacked cuboidal titanium nitride and mixed metal carbonitride inclusions and, instead, included relatively small, generally spherical oxide inclusions. We observed that the relatively small, generally rounded oxide inclusions are well tolerated by (*i.e.*, would not heavily score) the wire drawing equipment, substantially reducing the incidence of wire surface defects, and are much less likely to concentrate stresses in the wire to a degree resulting in wire fracture during drawing or when subjected to fatigue over time.

10. The very substantial change in microstructure produced by the chemistry modifications we made was entirely unexpected and very significant. The change was not merely a slight adjustment to microstructure, but unexpectedly resulted in a fundamentally different and well tolerated microstructure. Fortunately, the new microstructure of the alloy directly addressed the microstructural problems in the conventional MP35N alloy.

11. As discussed in detail in the Application, an apparent result of the above-discussed fundamentally different microstructure of the small-diameter wire produced from the alloy described in the Application exhibits very substantially improved fatigue resistance relative to conventional MP35N alloy. Table 9 of the Application, for

example, shows that at 100 ksi, a stress level similar to that to which cardiac pacemaker leads are subjected in service (*i.e.*, implanted in the body), wire formed from the alloy described in the Application withstood at least 797% the number of cycles in rotary beam fatigue testing than wire produced from conventional MP35N alloy, and the modified alloy had a fatigue endurance limit of between 100-110 ksi versus the 90 ksi limit of the conventional alloy. This improvement in fatigue properties was very significant, was surprising to me and my co-inventors, and was not expected even after we observed the fundamentally altered microstructure of the alloy of the Application. The unexpectedly significantly improved fatigue resistance of the modified alloy directly addressed the above-mentioned long felt need in the medical device industry for a biocompatible MP35N-type alloy useful for pacemaker leads and other surgically implanted components having a reduced incidence of fatigue-induced fracture.

**Smith U.S. Patent No. 3,356,542**

12. I have thoroughly reviewed U.S. Patent No. 3,356,542 issued to Smith ("Smith"). Smith does not describe or suggest an alloy that includes less than 30 ppm of nitrogen. Although Smith does state that the alloy described in that patent should include "no more than 0.05%" nitrogen, that level is more than 15 times the maximum nitrogen level critical to the invention described in the Application. Smith does not describe or suggest that there is any benefit whatsoever to limiting the nitrogen level in the alloy of that patent to less than 30 ppm, or even to very small, ppm range, concentrations.

13. Given that Smith does not state or suggest that that the alloy in that patent has or would benefit from having less than 30 ppm nitrogen, or even very low (ppm range) nitrogen levels, the alloy of Smith would certainly have included at least 50 ppm nitrogen. For example, 50 ppm is the minimum level of nitrogen found in conventional MP35N alloy. Although Smith does refer offhand to vacuum melting, such techniques were well known at the time, and Smith does not state or suggest that melting under vacuum should be done for reducing alloy nitrogen levels or otherwise. Smith does not state or suggest any reason why one would have undertaken the involved, time-

consuming, and costly steps necessary to limit nitrogen in the alloy described in Smith to less than 30 ppm or to any other extremely low level.

14. Absent limiting nitrogen to these very low levels recited in claim 1, alloy microstructure could not be substantially free of titanium nitride and mixed metal carbonitride inclusions. Also, Smith does not specifically describe or otherwise suggest a microstructure that is substantially free of titanium nitride and mixed metal carbonitride inclusions. Accordingly, Smith does not teach or suggest an alloy having a microstructure that is substantially free of titanium nitride and mixed metal carbonitride inclusions and, instead, includes well-tolerated substantially spherical oxide inclusions, as is recited in claim 1.

**Thielmann U.S. Patent No. 3,241,954**

15. I have thoroughly reviewed U.S. Patent No. 3,241,954 issued to Thielmann ("Thielmann"). I conclude that Thielmann is directed to alloys that differ significantly from the alloys described in Smith. I reach this conclusion based on the fact that the Smith and Thielmann alloys differ in at least the following ways:

- The Thielmann alloy lacks any appreciable level of molybdenum, while the Smith alloy includes 7-16% molybdenum.
- The Thielmann alloy includes 4-16% tantalum, while the Smith alloy lacks any appreciable level of tantalum.
- The Thielmann alloy includes 5-15% tungsten, while the Smith alloy lacks any appreciable level of tungsten.
- The Thielmann teaches that its alloy must not include more than 3.5% nickel, while the Smith alloy includes 5-45% nickel.
- The Thielmann alloy includes 0.1-1.3% carbon, while the Smith alloy includes no more than 0.05 % carbon.

16. The above differences are so significant that it is not correct to conclude that Thielmann teaches "an analogous cobalt-base alloy" relative to Smith. Instead, the alloys differ so substantially that one would not consider Thielmann pertinent when seeking out prior art relevant to modifying the properties of the alloy described in Smith.

**Crook U.S. Patent No. 4,353,742**

17. I have thoroughly reviewed U.S. Patent No. 4,353,742 issued to Crook ("Crook"). I conclude that Crook is directed to alloys that differ significantly from the alloys described in Smith. I reach this conclusion based on the fact that the Smith and Crook alloys differ in at least the following ways:

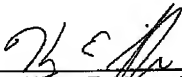
- The Crook alloy includes 27-35% chromium, while the Smith alloy includes 13-25% chromium.
- The Crook alloy may include up to 0.3% boron, while the Smith alloy includes no more than 0.05% boron.
- The Crook alloy may include up to 2.25% carbon, while the Smith alloy includes no more than 0.05% carbon.

18. The above differences are so significant that it is not correct to conclude that Crook teaches "an analogous cobalt-base alloy" relative to Smith. Instead, the alloys differ so substantially that one would not consider Crook particularly pertinent when seeking out prior art relevant to modifying the properties of the alloy described in Smith .

\* \* \* \*

19. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or document or any registration resulting therefrom.

Date: 08/24/2007

  
\_\_\_\_\_  
Henry E. Lippard

## EXHIBIT 2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of Forbes Jones et al.	:	
	:	COBALT-NICKEL-CHROMIUM-
Group Art Unit 1742	:	MOLYBDENUM ALLOYS WITH
	:	REDUCED LEVEL OF TITANIUM
Serial No. 10/656,918	:	NITRIDE INCLUSIONS
	:	
Filed September 5, 2003	:	
	:	Confirmation No. 8375
Examiner Jesse Roe	:	

DECLARATION OF ROBERT J. MYERS

Pittsburgh, Pennsylvania 15222-2312

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

1. I, Robert J. Myers, declare as follows:
2. I am a citizen of the United States and currently reside at 7435 Inverness Commons, Fort Wayne, Indiana.
3. I am over the age of eighteen and am competent to make the statements in this Declaration.
4. I am named as an inventor on the above-identified U.S. patent application ("the Application"), and I am thoroughly familiar with the Application and the claims currently pending in the Application. I also am thoroughly familiar with the alloy described in the Application and with the surgical implant products made from the alloy.



5. I currently hold the position of Executive Vice President of Fort Wayne Metals Products Research Corporation ("FWM"), Fort Wayne, Indiana, where I began working in 1998. I am responsible for business development and all commercial activity within FWM. As such, I am thoroughly familiar with the production, marketing, and sales of all FWM's products. Prior to joining FWM, I was employed at ATI Allvac, a business of Allegheny Technologies Incorporated, where I was a Product Manager responsible for the company's marketing activity associated with Allvac's entry into rod and coil specialty metals and titanium alloys. Prior to my employment at Allvac, I held various financial and marketing positions with Haynes International, a world leader in the market for cobalt and nickel base alloys. I have been an active member of the International Organization on Shape Memory and Superelastic Technologies (SMST), ASM International, and the Indiana Medical Device Manufacturers Council.

6. Since 2003, FWM has purchased rods and coils of a particular cobalt-nickel-chromium-molybdenum alloy from ATI Allvac having a chemistry and microstructure that falls squarely within at least Claim 1 of the Application. Specifically, the ATI Allvac alloy has the chemistry and microstructure recited in the current form of the Application's Claim 1. FWM processes the ATI Allvac alloy into small diameter wire of several diameters, and markets and sells the small diameter wire as 35N LT<sup>®</sup> wire for use in surgical implant products. Medical device companies purchase FWM's 35N LT wire for use in a number of surgical implant applications, including cardiac pacemaker and defibrillator leads and stylets, catheters, orthopedic cables, and stents.

7. From the time FWM began selling 35N LT wire I have been responsible for all marketing and sales of the product. As such, I am thoroughly familiar with the quantities of 35N LT wire FWM has sold and the gross revenues for such sales, and I routinely interact with FWM's customers for the product and request and obtain comments from those customers about their experiences using the product.

8. FWM has enjoyed incredible success selling 35N LT wire for use in surgical implant applications. FWM has generated more than \$6M in gross revenues from sales of 35N LT wire since it began selling the product in mid-2003. The following chart lists the number of discrete orders, the total weight, and the total length in linear

feet of 35N LT wire that FWM has sold to manufacturers of surgical implant devices in the years 2003-2006. Figure 1 graphically depicts the number of discrete orders (each order is assigned a distinct "part number") that FWM filled for 35N LT wire in each of years 2003-2006. Figure 2 graphically depicts the total linear feet of 35N LT wire FWM shipped in each of years 2003-2006.

Year	2003	2004	2005	2006
Number of Parts	22	99	130	253
Number of Invoices	23	140	270	483
Linear Feet (thousand feet)	357	19,273	55,190	107,323

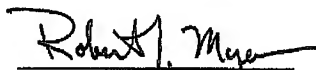
9. The figures in the above table and in the attached figures tell a compelling story of the very substantial market demand that has developed for 35N LT wire since its introduction. FWM filled its first commercial order for 35N LT wire in June of 2003. In the entire second half 2003, FWM filled 15 orders for a total of about 357,000 linear feet of 35N LT wire. In 2004, the number of filled orders quadrupled and, as is evident from the fact that FWM shipped over 19 million feet of wire that year, the average order in 2004 was substantially larger than in the prior year. In 2005, market demand for the wire accelerated – the number of discrete orders increased to 170% of the prior year's level and the total length of wire shipped, just over 55 million linear feet, was about 280% of the 2004 figure. Sales continued to grow in 2006 – orders increased to 150% of the prior year's number and total linear feet shipped advanced to 190% of the prior year's total. Therefore, per-year increases in product sales have been very significant, and this trend is continuing so far through 2007. The tremendous commercial success of 35N LT wire is perhaps better shown by the increase in the three-year period from 2004-2006. In 2006 the number of orders shipped was over 260%, and the total linear feet shipped was over 550% of the 2003 figures. I believe that this sales data convincingly shows that FWM's 35N LT small diameter wire product has proven to be a tremendous commercial success.

10. A number of different commercially available alloys are suitable for use in surgical implant applications such as in cardiac pacemaker and defibrillator leads and orthopedic cables, and stents. Although medical device manufacturers choose from among these alloys for these surgical implant applications based on a number of factors, chief among them is the fatigue resistance of the alloy (for example, fracture due to fatigue is the primary failure mechanism for cardiac pacemaker leads). Given the understandable importance of resistance to fatigue-induced fracture in surgical implant applications, application in which the product will be implanted in the body and cannot be retrieved and replaced without surgery, alloy cost is not of primary importance to surgical implant device manufacturers. In these applications, manufacturers seek out and purchase otherwise suitable (biocompatible) alloys having the best fatigue resistance properties since doing so will reduce the possibility of device failure.

11. The substantial commercial success that FWM has had with 35N LT wire is directly attributable to its substantially improved fatigue resistance relative to other alloys suitable for use in surgical implant applications. As manufacturers of pacemaker leads and related products have become familiar with the significantly improved fatigue resistance of 35N LT wire, they increasingly prefer the product over other available wire products suitable for their applications. I do not base this conclusion only on the substantial, rapid, and continuing increase in FWM's sales of 35N LT wire and on the fact that 35N LT wire has largely displaced other available biocompatible alloys for use in several surgical implant applications. I also base this conclusion on direct feedback from customers for 35N LT wire for use in certain surgical implant applications – those customers state that they chose FWM's 35N LT wire over wire formed from other available alloys because of the FWM product's superior fatigue resistance.

12. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or document or any registration resulting therefrom.

Date: 9/7/2007

  
Robert J. Myers

**35N LT**  
**# of Part Numbers per Year**

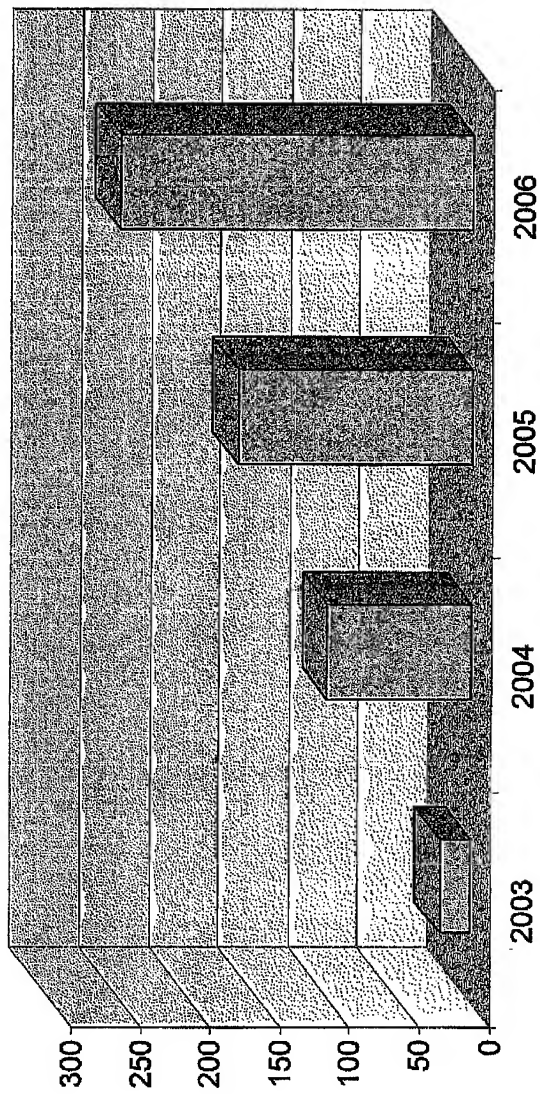


FIGURE 1

**35N LT**  
**Total Feet per Year**

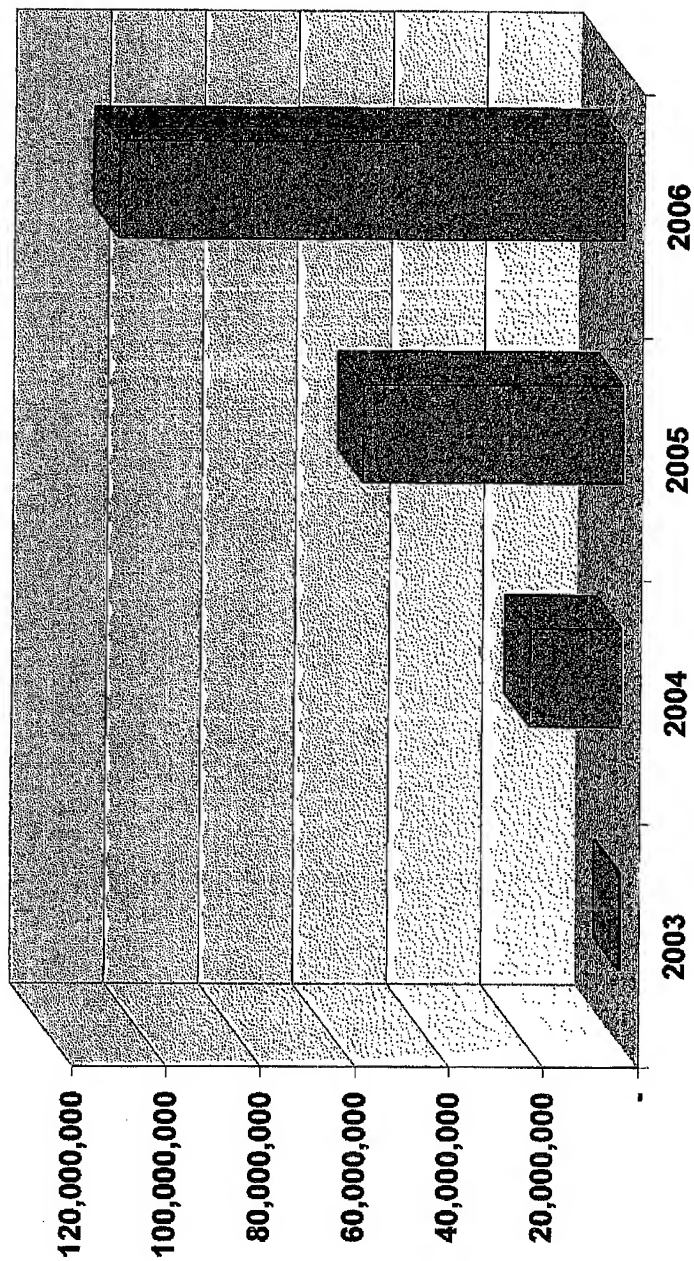


FIGURE 2